

JAN 14 2013

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K121706

1. Submitter Information:

Application Correspondence:

Contact Person: Pinjung Chen

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Date of submission: May 18th, 2012

Applicant:

Company Name: FORA Care Inc.

Contact Person: Sophia Wu

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2. Device name:

Proprietary name: FORA V10 No Code Blood Glucose Monitoring System, model
TD-4244

Regulatory information:

- A. Regulation section: 21 CFR 862.1345 Glucose Test System,
21 CFR 862.1660 Single Analyte Control
- B. Classification: Class II, Class I
- C. Product Code: NBW, System, Test, Blood Glucose, Over The Counter

CGA, Glucose Oxidase, Glucose, JXX, Single Analyte
Control

D. Panel: Chemistry (75)

3. Intended Use:

FORA V10 No Code Blood Glucose Monitoring System, model TD-4244, is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. The meter contains some speaking functions but has not been validated for use by visually impaired users. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

This system is intended to be used by a single patient and should not be shared.

FORA V10 test strips are for use with FORA V10 No Code Blood Glucose Monitoring System, model TD-4244, to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, forearm, upper arm calf and thigh.

The FORA control solutions can only be used with FORA V10 No Code Blood Glucose Monitoring System, model TD-4244, and the FORA V10 test strips to check that meter and test strips are working together properly.

The alternative site testing in FORA V10 No Code Blood Glucose Monitoring System, model TD-4244, can be used only during steady-state blood glucose conditions.

4. The Indications for Use is identical to K093035. The Indications for Use can be found in Section 8.

5. Device Description:

The system consists of three main products: the meter, test strips, and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only FORA V10 test strips and FORA control solutions with the FORA V10 No Code Blood Glucose

Monitoring System, model TD-4244.

6. Substantial Equivalence Information:

- A. Predicate device name: FORA V10 Blood Glucose Monitoring System
- B. Predicate K number: K093035
- C. Comparison with predicate:

The modified FORA V10 No Code Blood Glucose Monitoring System has the following similarities to the predicate device:

- Same intended use.
- Same operating principle.
- Same functions and physical appearance.
- Same fundamental scientific technology.
- Incorporate the same basic circuit design.
- Incorporate the same materials.
- Same shelf life.
- Same user interface and software.
- Packaged using the same materials.
- Manufactured by the same process.

The modifications:

- 510(k) applicant for the device is FORA Care Inc.
- Labeling changes due to the modification.

7. Test Principle:

The detection and measurement of glucose in blood is by an electrochemical biosensor technology using glucose oxidase.

8. Performance Characteristics:

The FORA V10 No Code Blood Glucose Monitoring System has the same performance characteristics as the predicate device.

Software verification and validation testing confirmed that the performance, safety and effectiveness of the FORA V10 No Code Blood Glucose Monitoring System are equivalent to the predicate device.

9. Traceability:

FORA V10 No Code Blood Glucose Monitoring System is compared to the YSI 2300 Glucose Analyzer in the Accuracy studies. The YSI is calibrated with NIST (SRM) 917A reference material. Test strips have been cleared under predicate k093035. Control Solutions were previously cleared under k093724.

10. Conclusion:

Based on the information provided in this submission, the FORA V10 No Code Blood Glucose Monitoring System is substantially equivalent to the predicate FORA V10 Blood Glucose Monitoring System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

January 14, 2013

FORA Care, Inc.
c/o Pinjung Chen
6F, NO.127, Wugong 2nd
Rd., Wugu District
New Taipei City, China (Taiwan) 24888

Re: k121706

Trade/Device Name: FORA V10 No Code Blood Glucose Monitoring System,
model TD-4244
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II,
Product Code: CGA, NBW, JJX
Dated: January 4, 2013
Received: January 7, 2013

Dear Pinjung Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Ruth A. Chesler

for Courtney H. Lias, Ph.D
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k121706

Device Name: FORA V10 No Code Blood Glucose Monitoring System, model TD-4244

Indications for Use:

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FORA V10 test strips are for use with FORA V10 No Code Blood Glucose meter model TD-4244 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, forearm, upper arm calf and thigh.

The FORA control solutions can only be used with FORA V10 No Code Blood Glucose meter, model TD-4244 and the FORA V10 test strips to check that meter and test strips are working together properly.

The alternative site testing in FORA V10 No Code Blood Glucose Monitoring systems model TD-4244 can be used only during steady-state blood glucose conditions.

Prescription Use
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k121706